# PHI-TEN USA, INC.

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May 3, 2005

MAY 1 0 2005

Dr. Robert J. Moore
Branch Chief, Compliance & Enforcement Branch
Office of Nutrition Products, Labeling & Dietary Supplements
Food & Drug Administration (HF S-800)
5100 Paint Brush Parkway
College Park, Maryland 20740

Re: Aqua Gold™, Dietary Supplement

Dear Dr. Moore:

Pursuant to 21CFR§101.93 of the Federal Food Drug, and Cosmetic Act, Phi-Ten USA, Inc. hereby notifies the Food and Drug Administration that it has begun commercializing Aqua Gold™ Dietary Supplement.

### I. Dietary Supplements containing colloidal gold:

Aqua Gold<sup>™</sup> is labeled and promoted with statements provided for in Section 403 (r)(6) of Federal Food, Drug and Cosmetic Act. Phi-Ten USA, Inc. will market Aqua Gold <sup>™</sup> for use of dietary supplement at a level of two tablespoons (30 ml)/day.

#### II. Evidence of Safety:

Aqua Gold<sup>™</sup>, when used under the conditions recommended in the indicated labeling, is reasonably expected to be safe. The active ingredient, colloidal gold has been used and studied nationwide for many years at this dose level with an excellent tolerance profile (Refer to page 3).

#### III. Manufacturer:

Aqua Gold<sup>™</sup> is manufactured and packaged by Phild Co., Ltd., 678 Tearaimizu-cho, Karasumadori, Nishikikoji-kado, Nakagyo-ku, Kyoto, 604-8152 Japan. Aqua Gold<sup>™</sup> is imported and distributed by Phi-Ten USA, Inc., 1860 W. Carson Street, Suite 101, Torrance, California 90501.

#### IV. Health Claim:

Aqua Gold<sup>TM</sup> bears the label "Dietary Supplement." The display panel bears the following claim, "Natural mineral supplement containing colloidal gold." Aqua Gold<sup>TM</sup> does not bear any health claims. The label includes the disclaimer, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

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# V. Active Ingredient:

The principal display panel bears the following structure/function claim, including the pure colloidal gold (10 ppl) and purified water (99.9%). No other dietary ingredient is contained in the supplement.

# VI. Responsible Party:

Pursuant to 21CFR§101.93(c), please be advised that the information contained in the complete and accurate, and we have substantiation on file that this claim is truthful and not misleading.

If you have any questions, please feel free to contact me.

Sincerely yours,

Masayoshi Hirano General Manager

Encl.

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#### REFERENCES

- Abraham, GE, MD; Souhaila A. McReynolds; Joel S. Dill, PhD
   Effect of Colloidal Metallic Gold on Cognitive Functions: A Pilot Study, Front. Persp. 7:39-41, 1998
- 2. Abraham, GE Himmel, PB: Management of Rheumatiod Arthritis: Rationale for the Use of Colloidal Metallic God, J Nutr. Med. 7:295-305,1997
- 3. Epstein, WV, et al: Effect of Parenterally Administered Gold Therapy on the Course of Adult Rheumatoid Arthritis, Ann. Int. Med., 114:437-444, 1991
- 4. Mahdihassan, S: Cinnabar-Gold as the best Alchemical Drug of Longevity, called Makaradhwaja in India, Am. J. Chinese Med., 13:93-108, 1985

May be mixed with water or juice Take two tablespoons (30mL) daily. As a dietary supplement,

PREVENT ANY DISEASE.

+Daily value not established

lngredients:

Colloidal gold

Total Carbohydrates

Amount Per Serving

Servings per container

Supplement Facts

Protein

muibo2

1st lstoT

Calories

Serving size

Cholesterol

NOT INTENDED TO DIAGNOSE, TREAT, CURE OR

FOOD AND DRUG ADMINISTRATION. THIS PRODUCT IS THESE STATEMENTS HAVE NOT BE EVALUATED BY THE

Purified water, 99.9% pure colloidal gold (10 ppt)

\*Percent Daily Values are based on a 2,000 calorie diet

60

60

60

60

60

0

% Daily Value\*

about 17

2 tablespoons (30 mL)

+ 1qq01

%0

%0

%0

%0

%0

0

#### Directions:

AQUA GOLD Phiten

# PRODUCT OF JAPAN

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Torrance, CA 90501 1860 W. Carson St., Suite 101 Phi-Ten USA Inc.

Distributed by:

Visit us at www.phitenusa.com

1-800-7-PHITEN

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containing colloidal gold Natūral mineral supplement

### DIETARY SUPPLEMENT

Phiten Special Members Only